

Remarks

The application has been reviewed in light of the Official Action mailed June 15, 2006. Claims 25, 50 and 51 are amended. Claim 39 is cancelled. Claims 25-38, 40-48, 50 and 51 are pending in the application.

No new matter is introduced by the amendments. The amendments are supported by matter disclosed in paragraphs [0004], [0005], [0013], [0049]-[0051], [0084], [0085], and [0090] of the specification.

The Examiner rejected claims 25, 27-34, 36, 38, 50 and 51 under 35 U.S.C. 102(b) as being anticipated by Berk (US 6,017,550). The Examiner rejected claims 25-30, 32-37, 43, 44, 47, 50 and 51 under 35 U.S.C. 102(b) as being anticipated by Paul (US 6,017,550). The Examiner rejected claims 25, 44, 48, 50 and 51 under 35 U.S.C. 102(b) as being anticipated by Hsia (US 6,294,166). The Examiner rejected claims 25, 44, 45, 50 and 51 under 35 U.S.C. 102(b) as being anticipated by Murad (US 5,804,594). The Examiner rejected claims 25, 26, 41-44 and 46 under 35 U.S.C. 103(a) as being unpatentable over Berk. The Examiner rejected claims 25 and 38-40 under 35 U.S.C. 103(a) as being unpatentable over Schlothauer et al. (WO 99/65326).

Applicants request that the Examiner reconsider the rejection of claim 25 because as amended claim 25 requires "a composition having less than 3% fat" and that "the composition comprises a protein component comprising whey powder and lactase

in the following approximate effective proportions: between about 95% to about 100 % by weight of whey powder, and between about 1% to about 5 % by weight of lactase.”

Applicants submit that Berk does not anticipate the claimed invention because Berk disclosing the step of administering a composition with a fat content greater than 3%. The Examiner cites Table I of Berk as demonstrating that Berk discloses the step of administering a composition of less than 3% fat. However, Berk discloses that Table I represents the ingredients for Fibrim 300® and that this fiber is a component of the compositions in Tables II and III. (col. 10, l. 4-7; col. 10 l. 57-61). Berk discloses that it is the compositions in Tables II and III that are administered to infants and adults. (col. 10 l. 66-67). The percentage fat in these compositions ranges from 19-31% for infants and 8-16% for adults. Thus, Berk does not disclose the step of administering “a composition having less than 3% fat[.]”

Applicants also submit that Berk, Paul, Hsia, Murad and Schlothauer do not anticipate amended claim 25 because they do not disclose “a protein component comprising whey powder and lactase in the following approximate effective proportions: between about 95% to about 100 % by weight of whey powder, and between about 1% to about 5 % by weight of lactase.” As indicated in the Official Action, these references do not disclose the limitations of original dependent claim 39. As a result, these references do not disclose the limitations of amended claim 25.

The Examiner states that it would be obvious to one skilled in the art to “make a food product containing lactase and whey and administer it to a subject as taught by Schlothauer.” (page 11). However, Schlothauer does not disclose administering a com-

position that contains lactase and whey powder. First, Schlothauer does not disclose administering whey powder but hydrolysed whey protein. The specification to the present Application notes that “[w]hey powder is typically a mixture of materials including, but not limited to lactose, protein, lactic acid and ash, and is one example of complex mixture that can be used as bulking agent. Whey (not whey protein concentrate) is a useful ingredient in an enteral feeding programs of mammals.” (par [00049]). Further, the Examiner notes that Schlothauer discloses that the process includes removing residual lactose by treatment with lactase. However, Schlothauer does not disclose administering the whey powder to a mammal along with lactase. Lactase is simply used during the processing stage. The Examiner states that one skilled in the art would be motivated to modify the disclosure in Schlothauer to incorporate the amounts of whey protein and lactase as present in claim 25 because it is a matter of routine optimization. However, Applicants submit that one skilled in the art would not be motivated to modify Schlothauer so as to administer whey powder in conjunction with lactase because Schlothauer discloses a method in which lactase is applied during processing to remove residual lactose. With the residual lactose removed, one skilled in the art would not be motivated to add additional lactase. Based on the foregoing Applicants respectfully submit that claim 25 is not obvious over the cited references.

Applicants request that the Examiner reconsider the rejection of claim 50 because as amended claim 50 requires a “method for providing critical care to a mammal with an energy deficiency by reducing the energy deficiency in the mammal comprising

the step of administering to the mammal a diet consisting of a critical care feeding program that consists of an energy promoting effective amount of a composition having less than 3% fat comprising an effective proportion of components.”

As noted above, Berk does not anticipate amended claim 50 because Berk does not disclose the step of administering “a composition having less than 3% fat[.]” Further, Berk does not anticipate amended claim 50 because Berk discloses a method of administering a composition “to control infantile colic and diarrhea and adult constipation and diarrhea.” (Abstract). Berk does not disclose a “method for providing critical care to a mammal with an energy deficiency by reducing the energy deficiency in the mammal.” Further, Berk does not disclose that the diet of the infant is limited to the composition disclosed in Berk. As a result, Applicants submit that amended claim 50 is not anticipated by Berk.

Applicants submit that Paul does not anticipate amended claim 50 because Paul discloses administering a composition as a dietary supplement. (See col. 2 l. 30-33). This indicates that Paul discloses a method of administering a composition that is only a component of the overall diet. Paul does not disclose administering a diet that consists “of a critical care feeding program that consists of an energy promoting effective amount of a composition having less than 3% fat comprising an effective proportion of components.”

Similarly, Hsia discloses administering a composition that supplements a mammalian diet. (col. 3 l. 42-43). Hsia does not disclose administering a diet that consists “of a critical care feeding program that consists of an energy promoting effective amount

of a composition having less than 3% fat comprising an effective proportion of components.”

Also, Murad does not anticipate the claimed invention because Murad only discloses “pharmaceutical compositions, as well as methods, to supplement collagen and elastic tissues and thicken the dermis for the treatment of wrinkles and other skin conditions.” (col. 1, l. 6-9). Murad does not disclose that a person’s diet is limited to the composition disclosed in Murad. As a result, Murad does not disclose administering a diet that consists “of a critical care feeding program that consists of an energy promoting effective amount of a composition having less than 3% fat comprising an effective proportion of components.”

Finally, Schlothauer does not anticipate the claimed invention because Schlothauer only discloses “a process for preparing a whey protein hydrolysate containing bioactive peptides.” (p. 3 l. 36-37). Schlothauer does not disclose that a person’s diet is limited to the composition disclosed in Schlothauer. Schlothauer does not disclose administering a diet that consists “of a critical care feeding program that consists of an energy promoting effective amount of a composition having less than 3% fat comprising an effective proportion of components.”

Applicants submit that one skilled in the art would not be motivated to combine Berk, Paul, Hsia, Murad, and Schlothauer because these references are directed to distinct objectives. As noted above, Berk discloses a method of administering a composition “to control infantile colic and diarrhea and adult constipation and diarrhea.” (Abstract). Paul discloses administering a composition to provide “for sustained energy and

nutrition to support an anabolic physiological state in humans.” (Abstract). Hsia discloses administering a composition “for use as a dietary supplement for promoting gastrointestinal health.” (Abstract). Murad discloses administering a composition “for the prevention and treatment of skin conditions.” (Abstract). Finally, Schlothauer discloses administering the hydrolyzed protein along with bioactive peptides in order to reduce systolic blood pressure. Since these references disclose compositions that are directed to distinct objectives and neither reference indicates that the teachings in those references could be combined or equally applied to each other, one skilled in the art would not be motivated combine these references.

Further, since none of these references disclose methods for “providing critical care to a mammal with an energy deficiency by reducing the energy deficiency” one skilled in the art would not be motivated to utilize the compositions disclosed in those references in such a manner. Similarly, since none of these references disclose a method in which the diet of a mammal consists “of a critical care feeding program that consists of an energy promoting effective amount of a composition having less than 3% fat comprising an effective proportion of components[,]” one skilled in the art would not be motivated to modify or combine the references to arrive at such a method.

Based on the foregoing, Applicants submit that amended claim 50 is not anticipated nor rendered obvious by the cited references.

Applicants request that the Examiner reconsider the rejection of claim 51 because as amended claim 51 requires “a composition having less than 3% fat” and that “the composition comprises a feed component comprising a non-soluble fiber.”

As noted above, Berk does not anticipate amended claim 50 because Berk does not disclose the step of administering “a composition having less than 3% fat[.]”

Applicants submit Paul, Hsia, Murad, and Schlothauer also do not anticipate claim 51 as amended. As indicated in the Official Action, these references do not disclose the limitations of original dependent claim 31. As a result, these references do not disclose a method that includes the step of administering “a composition having less than 3% fat” and that “the composition comprises a feed component comprising a non-soluble fiber.”

Further, Applicants submit that amended claim 51 is not obvious over the cited references because there is no motivation to modify or combine these references in accordance with amended claim 51.

As noted above, one skilled in the art would not be motivated to combine these references because these references are directed to distinct objectives.

Further, even if one skilled in the art were to combine these references there is no indication from any reference that such a combination would be in accordance with claim 51 as amended. As noted before, each reference is directed towards a distinct objective. In furtherance of those objectives, each reference discloses particular formulas. Considering the fact that the objectives are different, there is no way to predict how one skilled in the art would combine those references.

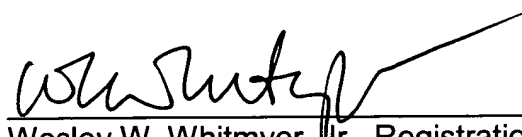
Thus, a method that requires step of administering "a composition having less than 3% fat" and that "the composition comprises a feed component comprising a non-soluble fiber" is not rendered obvious by these references.

The Examiner has required information under 37 CFR 1.105 regarding "All documentation relevant to the prosecution of the instant application concerning the public sale and knowledge of the invention" in order to consider patentability under 35 U.S.C. 102(b). Attached hereto is all documentation relating to the Examiner's requirement. Due to the limited information presented in some documentation, the Examiner is cautioned against extrapolating conclusions about their relevance towards patentability.

For the foregoing reasons, Applicants respectfully submit that all pending claims are patentable over the references of record, and earnestly solicits allowance of the same.

Respectfully submitted,

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